

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TEVA PHARMACEUTICALS  
INTERNATIONAL GMBH,  
CEPHALON, INC., and EAGLE  
PHARMACEUTICALS, INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES,  
LTD., and DR. REDDY'S  
LABORATORIES, INC.,

Defendants.

C.A. No. 21-695-CFC

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TEVA PHARMACEUTICALS  
INTERNATIONAL GMBH,  
CEPHALON, INC., and  
EAGLE PHARMACEUTICALS, INC.,

Plaintiffs,

v.

ACCORD HEALTHCARE, INC.,

Defendant.

C.A. No. 21-952-CFC

**JOINT CLAIM CONSTRUCTION CHART**

Pursuant to paragraph 15 of the Scheduling Order (No. 21-695-CFC, D.I. 22, 52), the parties respectfully submit the attached Joint Claim Construction Chart, addressing the claim construction positions of the parties regarding U.S. Patent Nos. 9,572,887 (“the ’887 patent”) and 11,103,483 (“the ’483 patent”) (collectively, “the

Asserted Patents”). The parties seek construction of one term from the ’887 patent (“a non-aqueous liquid composition”) and one term from the ’483 patent (“ready to use”). In addition, Plaintiffs propose, and Defendants do not contest, constructions for one term from the ’887 patent (“providing”) and one term from both the ’887 patent and ’483 patent (“stabilizing amount of an antioxidant”) consistent with this Court’s previous constructions of those terms in *Cephalon, Inc. v. Slayback Pharma LLC*, C.A. No. 17-1154-CFC, D.I. 394 (Apr. 27, 2020) (“stabilizing amount of an antioxidant”), and *Eagle Pharmaceuticals, Inc. v. Hospira, Inc.*, C.A. No. 18-1074-CFC, D.I. 108 (Dec. 28, 2020) (“providing”).

The parties agree that any terms in the asserted claims of the Asserted Patents that do not appear in the claim-construction charts below should be given their plain and ordinary meanings as understood by a person of ordinary skill in the art in light of the specification of the patent in which they appear, and thus do not require construction by the Court based on the information available the parties at this time. The parties may rely on additional intrinsic evidence to the extent that it is necessary to rebut arguments made by the other parties. The parties also may rely on any intrinsic evidence identified by any other party. The parties also may rely on extrinsic evidence.

In addition, Defendants note for the Court that they have identified various claim terms as indefinite in their Invalidity Contentions, which were served on

Plaintiffs consistent with the Court's Scheduling Order. The parties understand that the Court's usual practice is to decline to address indefiniteness arguments at the claim-construction stage and defer the adjudication of indefiniteness to a later stage in the litigation. *See, e.g., AuroMedics Pharma LLC v. Ingenus Pharms., LLC*, C.A. No. 20-1235-CFC-JLH, D.I. 55 (Aug. 5, 2021) (deferring indefiniteness until after claim construction); *Bial-Portela & CA S.A. v. Torrent Pharms. Ltd.*, C.A. No. 18-279-CFC, D.I. 63, at 21-24 (Oct. 17, 2019) (deferring indefiniteness until after claim construction). Given this practice, the parties agree that Defendants' indefiniteness arguments need not be addressed during claim-construction briefing, have not included them in the Joint Claim Construction Chart, and agree to defer them until trial or, if appropriate and with the Court's consent, summary judgment. Plaintiffs reserve the right to argue that any indefiniteness arguments (including those disclosed in Defendants' contentions) are not properly disclosed or preserved for trial for any reason other than the parties' agreement not to brief these issues at the claim construction stage. If the Court has a contrary preference, the parties request that the Court permit them to amend the Joint Claim Construction Chart accordingly.

Copies of the '887 patent and the '483 patent are attached hereto as Exhibits A and B, respectively.

Dated: June 17, 2022

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***Teva Pharmaceuticals International GmbH et al. v. Dr. Reddy's Laboratories, Ltd. et al.***  
**Civil Action No. 21-695-CFC**  
***Teva Pharmaceuticals International GmbH et al. v. Accord Healthcare, Inc.***  
**Civil Action No. 21-952-CFC**  
**Joint Claim Construction Chart**

<b>AGREED CONSTRUCTIONS</b>		
<b>Term</b>	<b>Patent and Claims</b>	<b>Parties' Proposed Construction</b>
"stabilizing amount of an antioxidant"	'887 patent, claim 14  '483 patent, claim 1	"any amount of an antioxidant that decreases the amount of bendamustine degradation after any time period and at any temperature" <sup>1</sup>
"providing"	'887 patent, claim 1	"making available"

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<sup>1</sup> Defendants contend that the claims containing this term are indefinite even under this construction, and by consenting to this construction do not waive their ability to argue that these claims are indefinite. Plaintiffs disagree that those claims are indefinite.

CLAIM TERM AT ISSUE IN U.S. PATENT NO. 9,572,887					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence <sup>2</sup>	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
"a non-aqueous liquid composition"	1-3, 14	<p>Plain and ordinary meaning, in view of the claims, specification, and prosecution history.</p> <p>If the Court determines that further construction is required, Plaintiffs propose that the Court adopt its prior</p>	<p><u>'887 Patent Claims</u> Claims 1-7, 14</p> <p><u>'887 Patent Written Description</u> Abstract, 2:65-3:1, 4:52-57, 4:57-61, 4:62-5:1, 5:1-5, 5:65-6:5, 6:53-66, 7:29-41, 10:19-21, 21:23-38, Examples 1-16, Tables 1-17</p> <p><u>'887 Patent Incorporated References</u> U.S. Patent Pub. No. 2013/0210879 ("Palepu '879"), at</p>	"a solution without water"	<p><u>'887 Patent Specification</u> at 1:24-35, 2:26-31, 2:39-45, 2:65-3:1, 4:1-33, 4:48-57, 5:5-27, 5:42-6:5, 6:35-67, 7:15-42, 10:23-42 (Ex. 1), 11:1-12:38 (Ex. 2), 13:29-14:67 (Ex. 5), 15:49-16:67 (Ex. 6), 17:33-20:25 (Ex. 7), 20:27-21:38 (Ex. 8), 21:40-22:59 (Ex. 9), 22:61-23:19 (Ex. 10), 23:20-24:10 (Ex. 11), 24:12-54 (Ex. 12), 24:56-25:39 (Ex. 13), 26:32-27:13 (Ex. 14), 27:15-53 (Ex. 15), 27:57-28:24 (Ex. 16). Tables 1-5, 7-</p>

<sup>2</sup> The parties reserve the right to rely on any intrinsic evidence on which the other relies, and any intrinsic evidence contradicting or otherwise rebutting any evidence on which the citing party relies. The parties also reserve the right to rely on extrinsic evidence and/or expert declaration or testimony in support of their proposed constructions or to rebut the other party's arguments and/or any expert declaration or testimony submitted by the other party.



CLAIM TERM AT ISSUE IN U.S. PATENT NO. 9,572,887					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence <sup>2</sup>	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
		construction of "a solution in which water does not make up a substantial portion and is not a significant solvent." <i>Eagle Pharms., Inc. v. Hospira, Inc.</i> , C.A. No. 18-1074-CFC-CJB, D.I. 108 (D. Del. Dec. 28,	[0124], Examples 2-7, Table 3; U.S. Patent Pub. No. 2011/0184036 ("Palepu '036"), at [0067], Claims 1, 14-15; U.S. Patent No. 8,344,006 ("Drager '006"), at 3:43-45, Claim 1; U.S. Patent Pub. No. 2013/0041003 ("Brittain '003"), at [0056]; U.S. Patent Pub. No. 2013/0041004 ("Drager '004"), at [0017], Claims 4-12; U.S. Patent Pub. No. 2006/0159713		17.  <u>'887 Patent File History:</u> Claims filed 6-16-2016, Non-Final Rejection of 8-12-2016, Response of 11-14-2016, Amended Claims filed 11-14-2016, Notice of Allowance of 12-16-2016.  <u>'707<sup>6</sup> file history:</u> Response of 4-25-2013, Office Action of 6-7-2013, Response of 9-4-2013, Notice of Allowance of 11-8-2013.

<sup>6</sup> U.S. Patent No. 8,609,707. Plaintiffs object to Defendants' suggestion that the '707 patent's file history is properly considered intrinsic evidence and reserve the right to challenge Defendants' characterization in claim construction briefing.

CLAIM TERM AT ISSUE IN U.S. PATENT NO. 9,572,887					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence <sup>2</sup>	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
		2020). <sup>3</sup>	("Brittain '713"), at [0056]  <u>'887 Patent File History</u> Original Application (June 16, 2016), Office Action (Aug. 12, 2016), Applicant Response (Nov. 14, 2016), Declaration of Steven L. Krill (Oct. 31, 2014), Notice of Allowance (Dec. 16, 2016), Examiner		<u>'831<sup>7</sup> file history</u> : Office Action of 11-22-2013, Response of 2-21-2014, Office Action of 3-31-2015, Response of 8-31-2015.  <u>'797<sup>8</sup> file history</u> : Claims of 2-2-2016, Office Action of 4-14-2016, Response of 7-22-2016, Notice of Allowance of 11-15-2016.

<sup>3</sup> Defendants contend that the claims containing this term are indefinite even under either claim-construction proposal that Plaintiffs advance. Plaintiffs disagree that those claims are indefinite.

<sup>7</sup> U.S. Patent No. 9,265,831. Plaintiffs object to Defendants' suggestion that the '831 patent's file history is properly considered intrinsic evidence for the '887 patent and reserve the right to challenge Defendants' characterization in claim construction briefing.

<sup>8</sup> U.S. Patent No. 9,572,797. Plaintiffs object to Defendants' suggestion that the '797 patent's file history is properly considered intrinsic evidence and reserve the right to challenge Defendants' characterization in claim construction briefing.

CLAIM TERM AT ISSUE IN U.S. PATENT NO. 9,572,887					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence <sup>2</sup>	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
			<p>Interview Summary (Dec. 22, 2016)</p> <p><u>'397 Patent<sup>4</sup> File History</u></p> <p>Office Action (Aug. 18, 2016), Declaration of Steven L. Krill (Oct. 31, 2014), Applicant Response (Nov. 15, 2016), Notice of Allowance (Jan. 5, 2017)</p> <p><u>'908 Patent<sup>5</sup> File History</u></p> <p>Office Action (Feb. 7,</p>		<p><u>'796<sup>9</sup> file history:</u></p> <p>Response of 7-22-2016, Notice of Allowance of 11-14-2016.</p>

<sup>4</sup> U.S. Patent No. 9,597,397.

<sup>5</sup> U.S. Patent No. 9,034,908.

<sup>9</sup> U.S. Patent No. 9,572,796. Plaintiffs object to Defendants' suggestion that the '796 patent's file history is properly considered intrinsic evidence and reserve the right to challenge Defendants' characterization in claim construction briefing.

CLAIM TERM AT ISSUE IN U.S. PATENT NO. 9,572,887					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence <sup>2</sup>	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
			<p>2014), Applicant Response (Apr. 9, 2014), Office Action (Apr. 29, 2014), Applicant Response (May 5, 2014), Office Action (May 14, 2014), Applicant Response (Aug. 14, 2014), Applicant Response (Oct. 14, 2014), Declaration of Steven L. Krill (Oct. 31, 2014), Applicant Response (Nov. 14, 2014), Office Action (Dec. 12, 2014), Notice of Allowance (Apr. 8, 2015)</p> <p><u>Prosecution History References</u> W.O. Patent Pub. No. 2010/126676</p>		

CLAIM TERM AT ISSUE IN U.S. PATENT NO. 9,572,887					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence <sup>2</sup>	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
			(“Labell”), at 2:17-26, 3:15-20; U.S. Patent Pub. No. 2010/0092474 (“Gallagher”), at [0498]; U.S. Patent Pub. No. 2010/0145266 (“Orlowski”), at [0070], [0123]; U.S. Patent App. No. 13/767,672 (“Palepu ’672”), at 14:9-13; U.S. Patent Pub. No. 2013/0210879 (“Palepu ’879”), at [006], [0124], Examples 2-7, Table 3; U.S. Patent Pub. No. 2012/0059000 (“Ren”), at [0235]; Spiegel et al., <i>Use of Nonaqueous Solvents in Parenteral</i>		

CLAIM TERM AT ISSUE IN U.S. PATENT NO. 9,572,887					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence <sup>2</sup>	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
			<i>Products</i> , 52 J. Pharm. Sci. 917, 921, 924, 926 (1963) (“Spiegel”); W.O. Patent Pub. No. 2013/142358 (“Sundaram ’358”), at [0038]; U.S. Patent App. No. 15/184488 (“Sundaram ’488”), at 8		

CLAIM TERMS AT ISSUE IN U.S. PATENT NO. 11,103,483					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
"ready to use"	1-8, 12-16	<p>Plain and ordinary meaning, in view of the claims, specification, and prosecution history.</p> <p>If the Court determines that further construction is required, Plaintiffs propose that the Court adopt the prior stipulated construction</p>	<p><u>'483 Patent Claims</u> Claims 1-8, 12-16</p> <p><u>'483 Patent Written Description</u> Abstract, 1:22-62, 2:13-21, 2:26-31, 2:60-67, 3:30-4:40, 5:17-31, 5:32-44, Examples 1-8, Tables 1-8</p> <p><u>'483 Patent File History</u> Original Application (July 12, 2019); Office Action (May 27, 2020); Office Action (Dec. 21, 2020); Examiner Interview Summary (Mar. 16, 2021);</p>	"prepackaged and able to be dispensed with minimal if any effort or preparation and without requiring further dilution"	<p><u>'483 Patent Specification</u> at Abstract, 1:58-62, 2:13-21, 2:26-29, 5:17-31.</p> <p><u>'483 Patent File History:</u> Original Claims of 7-12-2019, Office Action of 12-21-2020, Response of 5-20-2021, Response of 6-11-2021, Advisory Action of 6-2-2021, Examiner Interview Summary of 7-16-2021, Notice of Allowance of 7-26-2021.</p> <p><u>'707<sup>11</sup> file history:</u> Office Action of 1-25-2013, Response of 4-25-2013</p>

<sup>11</sup> U.S. Patent No. 8,609,707.

CLAIM TERMS AT ISSUE IN U.S. PATENT NO. 11,103,483					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
		of “able to be dispensed with minimal if any effort or preparation; prepackaged.” <i>Eagle Pharms., Inc. v. Slayback Pharma LLC</i> , C.A. No. 21-1256-CFC-CJB, D.I. 41 (D. Del.). <sup>10</sup>	Applicant Response (May 20, 2021), Office Action (June 2, 2021), Examiner Interview Summary (July 16, 2021), Notice of References Cited (July 16, 2021), Notice of Allowance (July 26, 2021), Notice of Allowance (Aug. 4, 2021)  <u>'707 Patent File History</u> Original Application (Jan. 28, 2011), Office Action (Oct. 9, 2012), Applicant Response (Nov. 30,		

<sup>10</sup> Defendants contend that the claims containing this term are indefinite even under either claim-construction proposal that Plaintiffs advance. Plaintiffs disagree that the terms are indefinite.



CLAIM TERMS AT ISSUE IN U.S. PATENT NO. 11,103,483					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendants' Proposed Construction	Defendants' Intrinsic Evidence
			<p>2012), Office Action (Jan. 25, 2013)</p> <p><u>Prosecution History References</u></p> <p>U.S. Patent Pub. No. 2006/0159713 (“Brittain ’713”); Treanda® Label 2008; “Ready to Use,” Medical Dictionary, <a href="https://medical-dictionary.thefreedictionary.com/ready-to-use">https://medical-dictionary.thefreedictionary.com/ready-to-use</a></p>		

<b>TERMS DEFENDANTS CONTEND ARE INDEFINITE<sup>12</sup></b>	
<b>Terms</b>	<b>Patent and Claims</b>
“a non-aqueous liquid composition”	’887 patent, all claims
“wherein the total impurities are less than about 5% as determined by HPLC at a wavelength of 223 nm after 15 months at a temperature of from about 5° C. to about 25° C.”	’887 patent, all claims
“the composition having less than about 5% peak area response of total impurities resulting from the degradation of the bendamustine, as determined by HPLC as a wavelength of 223 nm after at least 15 months at a temperature of from about 5° C. to about 25° C.”	’483 patent, all claims
“long-term storage stable”	’887 patent, claims 14-15
“stabilizing amount of an antioxidant”	’887 patent, claims 14-15 ’483 patent, all claims
“ready to use”	’483 patent, all claims

<sup>12</sup> As explained above, Defendants contend the following terms are indefinite regardless of which constructions ultimately apply to each respective term. While Defendants understand the Court’s practice is not to address indefiniteness issues at the claim-construction stage, this information has been included to further preserve these indefiniteness positions for the Court’s consideration at trial in this case, or, if appropriate and with the Court’s consent, at summary judgment. Plaintiffs disagree that the terms are indefinite and reserve the right to argue that any indefiniteness arguments (including those disclosed in Defendants’ contentions) are not properly disclosed or preserved for trial for any reason other than the parties’ agreement not to brief these issues at the claim construction stage.